

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 42-R-0020

FORM APPROVED
OMB NO. 0579-0036

CUSTOMER NUMBER: 1625

b6,b7c

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)Novartis Animal Vaccines, Inc. (Novartis) Health US, Inc.
1447 140th Street (B)(6) (B)(7)(c) 11/18/05
Larchwood, IA 5124

Telephone: (B)(6) (B)(7)(c)

A. G. D. WATKINS 03/14/0

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3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

INFORMATION

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		415	43	86	544
7. Hamsters		5,772		2,801	8,573
8. Rabbits		5	1,646		1,651
9. Non-human Primates					
10. Sheep					
11. Pigs		61		35	96
12. Other Farm Animals					
calves		30			30
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and apr Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(B)(6) (B)(7)(c)

DATE SIGNED

11/18/05

NOV 28 2005

Column E Explanation

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1. Registration Number: 42-R-0020

2. Number 86 (b)(4) of animals used in this study.

3. Species (common name) Guinea Pigs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

(b)(4) test. This test is the required (b)(4) release test specified in the USDA approved Production Outline which the USDA requires for products containing (b)(4). The procedure is a (b)(4) (b)(4)

(b)(4) test. This test is the required (b)(4) release test specified in the USDA approved Production Outlines which the USDA requires for products containing the (b)(4). The procedure is a (b)(4) in which death is the endpoint.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)

(b)(4) test. This is a USDA mandated test, refer to Item 6.

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6. What, if any federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9CFR 113.102)

(b)(4) test: USDA APHIS CVB, (b)(4)

(b)(4) test: USDA APHIS CVB, (b)(4)

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Column E Explanation

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1. Registration Number: 42-R-0020
2. Number 2801 of animals used in this study.
3. Species (common name) hamsters of animals used in the study.
4. Explain the procedure producing pain and/or distress.

(b)(4) test. This test is the required (b)(4) release test specified in the USDA approved Production Outlines which the USDA requires for products containing the (b)(4). The procedure is a (b)(4). In accordance with 9CFR 117.4.(e). animals are euthanized to prevent further pain and distress, if the (b)(4) illness progresses to a point when death is certain.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)

(b)(4) test. This is a USDA mandated test, refer to Item 6.

6. What, if any federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9CFR 113.102)

(b)(4) USDA APHIS CVB, (b)(4)

(b)(4) USDA APHIS CVB, (b)(4)

(b)(4) USDA APHIS CVB, (b)(4)

(b)(4) USDA APHIS CVB, (b)(4)

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information

Column E Explanation

1. Registration Number: 42-R-0020
2. Number 35 of animals used in this study.
3. Species (common name) pigs of animals used in the study.
4. Explain the procedure producing pain and/or distress.

(b)(4) test. This is the required (b)(4) release test specified in the USDA approved Special Outline and Production Outlines. The procedure is a vaccination/challenge model in which death is the endpoint.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below)

(b)(4)

6. What, if any federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9CFR 113.102)

This is the required (b)(4) release test specified in the USDA approved Special Outline and Production Outlines.

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Attachment 1:

Amended Column E Explanations, March 6, 2006

MAR - 8 2006

Column E Explanations Referencing APHIS Form 7023

2005 Annual Report of Research Facility: Registration Number 42-R-0020

Amended As of March 6, 2006

Number of Animals Used in the Study:

Eighty Six (86).

- (b)(4) for release of serials of
USDA regulated biological product (ie. vaccine).
- (b)(4) for release of USDA
regulated biological product (ie vaccine).

Species (common name) of Animals Used in the Study:

Guinea pig

Explanation of Procedure Producing Pain and/or Distress:

(b)(4) : This test is mandated by APHIS-Center for
Veterinary Biologics (CVB) in the licensing of vaccines to protect animals from the
effects of disease caused by infection (b)(4) This test is prescribed in Title
9 of the Code of Federal Regulations.

The test procedure is (b)(4)

(b)(4)

(b)(4) : This test is mandated by APHIS-Center for
Veterinary Biologics (CVB) in the licensing of vaccines intended to protect animals
from the effects of disease (b)(4) This test is prescribed in
Title 9 of the Code of Federal Regulations.

The test procedure (b)(4) death is
the prescribed endpoint.

As per 9 CFR 117.4 (e), and in accordance with APHIS-CVB communication of April 1,
2004 (RE: VBN 04-09), collaborative initiatives are in progress with APHIS-CVB to
obtain approval for a "non-death" endpoint that would allow humane methods of
euthanasia. The successful outcome of these initiatives would result in modifications to
the APHIS-CVB approved production outlines for each of the respective products.

Scientific Justification As to Why Pain and/or Distress Could Not Be Relieved:

Both tests are codified in the Title 9 Code of Federal Regulations. These codified tests
methods have been promulgated by APHIS-CVB and to date, APHIS-CVB have not
published guidance to licensed biological manufacturers that would allow for the use of
drugs such as pain relievers to reduce pain and suffering prior to attaining the study
endpoint.

To our knowledge, APHIS-CVB has not determined, nor communicated, what impact,
use of drugs such as pain relievers would have on the validity of these assays.

Identification of Federal Regulations Requiring This Procedure:

- USDA (APHIS-CVB):
- USDA (APHIS-CVB): (b)(4)

(B)(6) (B)(7)(c)

Date: 3-6-06

MAR - 8 2006

Column E Explanations Referencing APHIS Form 7023

2005 Annual Report of Research Facility: Registration Number 42-R-0020

Amended As of March 6, 2006

Number of Animals Used in the Study:

Two Thousand, Eight Hundred and One (2,801)

Species (common name) of Animals Used in the Study:

Hamster

Explanation of Procedure Producing Pain and/or Distress:

(b)(4) : These test are mandated by APHIS-Center for veterinary biologics (CVB) in the licensing of vaccines to protect animals from the effects of disease caused by infection with (b)(4). These tests are prescribed in Title 9 of the Code of Federal Regulations.

These procedures (b)(4) death is the prescribed endpoint.

As per 9 CFR 117.4 (e), and In accordance with APHIS-CVB communication of April 1, 2004 (RE: VBN 04-09), collaborative initiatives are in progress with APHIS-CVB to obtain approval for a "non-death" endpoint that would allow humane methods of euthanasia. The successful outcome of these initiatives would result in modifications to the APHIS-CVB approved production outlines for each of the respective products.

Scientific Justification As to Why Pain and/or Distress Could Not Be Relieved:

These tests are codified in the Title 9 Code of Federal Regulations. These codified tests methods have been promulgated by APHIS-CVB and to date, APHIS-CVB have not published guidance to licensed biological manufacturers that would allow for the use of drugs such as pain relievers to reduce pain and suffering prior to attaining the study endpoint.

To our knowledge, APHIS-CVB has not determined, nor communicated, what impact, use of drugs such as pain relievers would have on the validity of these assays.

Identification of Federal Regulations Requiring This Procedure:

- USDA (APHIS-CVB):
- USDA (APHIS-CVB):
- USDA (APHIS-CVB): (b)(4)
- USDA (APHIS-CVB):

(B)(6) (B)(7)(c)

Date: 3-6-06

MAR - 8 2006

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Column E Explanations Referencing APHIS Form 7023

2005 Annual Report of Research Facility: Registration Number 42-R-0020

Amended As of March 6, 2006

Number of Animals Used in the Study:

Thirty-five (35)

Species (common name) of Animals Used in the Study:

Swine

Explanation of Procedure Producing Pain and/or Distress:

(b)(4) : This test methodology was developed by the firm as a foundational component of obtaining product licensure by APHIS-Center for Veterinary Biologics (CVB). The data generated from the study was deemed by APHIS-CVB personnel to fulfill the requirements of measuring serial (b)(4) correlated to (b)(4) supporting product licensure.

The procedure (b)(4) for which death is the endpoint.

The organization has submitted data to APHIS-CVB in an effort to replace this in-vivo (b)(4) with a (b)(4) AHIS-CVB has determined that the correlative ability of (b)(4) was insufficient to ensure that serials of product released by this assay are adequately (b)(4)

As per 9 CFR 117.4 (e), and In accordance with APHIS-CVB communication of April 1, 2004 (RE: VBN 04-09), collaborative initiatives are in progress with APHIS-CVB to obtain approval for a "non-death" endpoint that would allow humane methods of euthanasia. The successful outcome of these initiatives would result in modifications to the APHIS-CVB approved production outlines for each of the respective products.

Scientific Justification As to Why Pain and/or Distress Could Not Be Relieved:

The (b)(4) as approved in the product production outline and related (b)(4) for which death is the prescribed end-point to evaluate the protective effect of the serial sample. Utilization of drugs, such as pain relievers, jeopardizes the validity of the (b)(4) assay (b)(4), invalidating (b)(4) as licensed.

Identification of Federal Regulations Requiring This Procedure:

USDA (APHIS-CVB). Production Outline and Special Outline as appropriate, as prescribed (b)(4)

(B)(6) (B)(7)(c)

Date: 3-6-06

MAR - 8 2006